COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 02/10/2003
C(2003) 3578

NOT FOR PUBLICATION

COMMISSION DECISION

of 02/10/2003

amending Decision C(2000)1407 on the marketing authorization for the medicinal product for human use

"PegIntron - Peginterferon alfa-2b"

(Text with EEA relevance)

ONLY THE FRENCH AND THE DUTCH TEXTS ARE AUTHENTIC.

COMMISSION DECISION

of 02/10/2003

amending Decision C(2000)1407 on the marketing authorization for the medicinal product for human use

"PegIntron - Peginterferon alfa-2b"

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EEC) No 2309/93 of 22 July 1993 laying down Community procedures for the authorization and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products[1], as amended by Commission Regulation (EC) No 649/98[2],

Having regard to Commission Regulation (EC) No 542/95 of 10 March 1995 concerning the examination of variations to the terms of a marketing authorisation falling within the scope of Council Regulation (EEC) No 2309/93[3], as amended by Commission Regulation (EC) No 1069/98[4], and in particular Article 8(3) thereof,

Having regard to the opinion of the European Agency for the Evaluation of Medicinal Products,

Whereas:

(1) The medicinal product "PegIntron - Peginterferon alfa-2b" entered in the Community register of medicinal products under Nos EU/1/00/131/032-050 and EU/1/00/131/001-031 authorised by Commission Decision C(2000)1407 of 25 May 2000, as amended, complies with the requirements set out in Regulation (EEC) No 2309/93.

(2) Schering Plough Europe submitted an application on 26 May 2003 pursuant to Article 6(1) set out in Regulation (EC) No 542/95.

(3) The European Agency for the Evaluation of Medicinal Products delivered a favourable opinion formulated on 26 June 2003 by the Committee for Proprietary Medicinal Products,

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[1] OJ No L 214, 24. 8. 1993, p. 1.
[2] OJ L 88, 24.3.1998, p. 7.
[3] OJ No L 55, 11.3.1995, p. 15
[4] OJ L 153, 27.5.1998, p. 11

(4) Decision C(2000)1407 should therefore be amended accordingly.

(5) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on Medicinal Products for Human Use,

HAS ADOPTED THIS DECISION:

Article 1

Decision C(2000)1407 is amended as follows:

1. Annex I is replaced by the Annex to this Decision.

Article 2

This Decision is addressed to Schering Plough Europe, Rue de Stalle, 73, 1180 Bruxelles, Belgique – Stallestraat, 73 – 1180 Brussel, België.

Done at Brussels, 02/10/2003

For the Commission
Erkki LIIKANEN
Member of the Commission